

REMARKS

Applicants respectfully request further examination and reconsideration in view of the above amendments and the arguments set forth fully below. In the Final Office Action mailed November 22, 2006, claims 1-20 have been rejected. In response, the Applicants have submitted the following remarks and amended claims 1 and 20. Accordingly, claims 1-20 are still pending. Favorable reconsideration is respectfully requested in view of the amended claims and the remarks below.

Information Disclosure Statement

Within the Office Action, it is stated that the Information Disclosure Statement filed on May 24, 2004 fails to comply with 37 C.F.R. §1.98(a)(3) because there is no translation in accordance with MPEP 609.05, or relevance statement. The Applicants respectfully submit that a new Information Disclosure Statement will be submitted under separate cover.

Rejections Under 35 U.S.C. §102

Claim 20 has been rejected under 35 U.S.C. §102(a) & (e) as being anticipated by U.S. Patent No. 6,668,188 to Sun et al. (hereinafter Sun). The Applicants respectfully disagree with this rejection.

Sun teaches a method of presenting information for evaluating the condition of chronically impaired cardiac patients based on long term assessment of activity trends, using a memoried implanted cardiac rhythm management device having a plurality of programmable parameters and one or more sensors for sensing one or more parameters related to an activity level of the patient (Sun, abstract). The Sun patent does not teach acquiring separate patient data, as well as implant data from an implantable cardiac device, nor does Sun teach generating a signature pattern of the patient. The Sun reference merely teaches collecting a memoried implanted cardiac rhythm management device with a plurality of programmable parameters to acquire data indicative of the

activity level of the patient and using that data along with accumulated sensor data to determine the activity level of the patient.

In contrast to the teachings of Sun, the present invention collects both implant data, as well as non-implant data, and synchronizes this data so that the synchronized data can be correlated in a signature pattern and be compared to determine the cardiac condition of the patient. It is important to note that neither Sun, nor any of the other cited references include a system or method that collects both data from an implanted device, as well as separate data from non-implanted means. The present invention is novel as it is able to not only collect both of these types of data, but also synchronizes the data, and correlates the synchronized data to determine a cardiac condition of the patient, and to generate a signature pattern of the patient.

Referring to page 7, paragraphs 25 and 26 of the present invention, the signature pattern, as claimed and described in the present invention, can be used to determine whether cardiac event has occurred in the patient, and how the implant reacted to, or was effected by the cardiac event. The signature pattern is also configured to determine the effectiveness of the current treatment, or to determine whether a new diagnosis is warranted, or to recommend a new treatment for the patient. Furthermore, the signature pattern of the present invention can determine the point at which treatment was applied to the patient and the effect the treatment had on the patient's implant and non-implant data. As stated previously, the Sun reference does not teach such a signature pattern being generated.

The independent claim 20 is directed to a method of determining a cardiac treatment for a patient having an electronic cardiac implant comprising acquiring patient data, acquiring implant data from the implant, correlating the patient data and the implant data with a correlating algorithm to determine a cardiac treatment for the patient and generating a signature pattern of the patient. As discussed above, Sun does not teach acquiring both patient data as well as implant data from the implant. For at least these reasons, the independent claim 1 is allowable over the teachings of Sun.

Claims 1-3 and 6-12 have been rejected under 35 U.S.C. §102(a) & (e) as being anticipated by U.S. Patent No. 6,647,287 to Peel, III et al. (hereinafter Peel). The Applicants respectfully disagree with this rejection.

Peel teaches a method and system for reconstructing and verifying aortic blood pressure waveforms from peripheral blood pressure waveform data using mathematical models (Peel, abstract). Within the Office Action it is stated that Peel teaches acquiring continuous radial or ulnar blood pressure with a tonometer or blood pressure sensor in an artery, and measures and acquires a plethysmographic blood pressure from the patient via their finger. However, Peel does not actually teach the step of outputting a signature pattern of the patient.

In contrast to the teachings of Peel, the system and method of the present invention includes synchronizing the non-implant cardiac data and the implant cardiac data. If the data is not analyzed or reviewed in real-time, the patient monitoring system can assign to the date and time when the data was acquired by use of an internal timing system such as an atomic clock. The implant data can be time synchronized with the non-implant data by the patient monitoring system based on the date and time when the implant and the non-implant data was acquired. If implant and non-implant data was not acquired during the same date and time, the implant data can be aligned with the non-implant data according to one or more fiducial points (present invention, pages 6-7, paragraph 24). The Peel reference does not teach synchronization as is taught and claimed in the present invention, and to generate a signature pattern of the patient.

Referring again to page 7, paragraphs 25 and 26 of the present invention, the signature pattern, as claimed and described in the present invention, can be used to determine whether cardiac event has occurred in the patient, and how the implant reacted to, or was effected by the cardiac event. The signature pattern is also configured to determine the effectiveness of the current treatment, or to determine whether a new diagnosis is warranted, or to recommend a new treatment for the patient. Furthermore, the signature pattern of the present invention can determine the point at which treatment

was applied to the patient and the effect the treatment had on the patient's implant and non-implant data. The Pell reference does not teach such a signature pattern being generated.

Claim 1 is directed to a method of analyzing cardiac data acquired from a patient having an electronic cardiac implant, the method comprises acquiring non-implant cardiac data from the patient, acquiring implant cardiac data from the implant, synchronizing the non-implant cardiac data and the implant cardiac data, correlating the non-implant cardiac data with the implant cardiac data to determine a cardiac condition of the patient, wherein the correlating step is carried out with a correlating algorithm, and outputting a signature pattern of the patient. As described above, Peel does not teach synchronizing the non-implant cardiac data and the implant cardiac data nor outputting a signature pattern of the patient. For at least these reasons, the independent claim 1 is allowable over the teachings of Peel.

Claims 2 and 3 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Peel. Accordingly, claims 2 and 3 are also allowable as being dependent upon an allowable base claim.

Claim 6 is directed to a method of determining a cardiac treatment for a patient having an electronic cardiac implant comprising acquiring non-implant cardiac data from the patient, acquiring implant cardiac data from the implant, correlating the non-implant cardiac data and the implant cardiac data to generate a signature pattern, and analyzing the signature pattern to determine a cardiac treatment for the patient. As stated previously, Peel does not teach generating a signature pattern as is taught and claimed in the present invention. For at least these reasons, the independent claim 6 is allowable over the teachings of Peel.

Claims 7-9 are dependent upon the independent claim 6. As discussed above, the independent claim 6 is allowable over the teachings of Peel. Accordingly, claims 7-9 are also allowable as being dependent upon an allowable base claim.

The independent claim 10 is also a method of developing criteria for diagnosis of cardiac condition in a patient having electronic cardiac implant, and includes the limitation of synchronizing non-implant cardiac data and the implant cardiac data. As described above, Peel does not teach synchronizing the non-implant cardiac data and the implant cardiac data, nor generating a signature pattern of the patient. For at least these reasons the independent claim 10 is allowable over the teachings of Peel.

Claims 11 and 12 are dependent upon the independent claim 10. as discussed above, the independent claim 10 is allowable over the teachings of Peel. Accordingly, claims 11 and 12 are also allowable as being dependent upon an allowable base claim.

Claims 15, 16 and 19 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,948,005 to Valikai et al. (hereinafter Valikai). The Applicants respectfully disagree with this rejection.

Valikai teaches gathering events/rate data with an implantable pace maker and displaying that data in a histogram format as a function of heart rate and event type, with multiple events being included in the display of each rate bin of the histogram (Valikai, abstract). Within the Office Action, column 17, lines 10-25 is cited as teaching acquiring data from the patient and from the implant. However, after reviewing the cited material in Valikai, it is clear that Valikai merely teaches an implantable pace maker for collecting implanted data, and no other means for collecting data, nor correlating such data, as no correlation occurs if only implantable data collection exists. Furthermore, Valikai does not teach the generation of a signature pattern of the patient.

In contrast to the teachings of Valikai, the method and system of the present invention teaches and claims collecting not only data from an implantable device, but also non-implantable device data, and synchronizing and correlating these two data collections to diagnose a cardiac condition of a patient, and further to generate a signature pattern of the patient.

Claim 15 is directed to a patient monitoring system for analyzing cardiac data acquired from a patient having an electronic cardiac implant comprising a transmitter that

generates a polling signal, a receiver that receives implant data when the implant responds to the polling signal, and a computer readable memory encoded with a software and program, the software program sets forth rules for a data acquisition module that acquires implant cardiac data from the implant and non-implant cardiac data from the patient, and an analysis module that correlates the implant cardiac data and the non-implant cardiac data and generates signature pattern from the correlation. As described above, Valikai does not teach a data acquisition module that acquires non-implant cardiac data from the patient and correlates the implant cardiac data and the non-implant cardiac data, nor generating a signature pattern. For at least these reasons, the independent claim 15 is allowable over the teachings of Valikai.

Claims 16 and 19 are dependent upon the independent claim 15. As discussed above, the independent claim 15 is allowable over the teachings of Valikai. Accordingly, claims 16 and 19 are also allowable as being dependent upon an allowable base claim.

Rejections Under 35 U.S.C. §103

Claims 5 and 14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Peel as applied to claims 1 and 10, in view of U.S. Patent No. 4,616,333 to Shimoni (hereinafter Shimoni). Claims 5 and 14 are dependent upon the independent claims 1 and 10. As discussed above, the independent claims 1 and 10 are allowable over the teachings of Peel. Accordingly, claims 5 and 14 are also allowable as being dependent upon an allowable base claim.

Claim 17 and 18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Valikai as applied to claim 15, in further view of U.S. Publication No. 2002/0099302 to Bardy (hereinafter Bardy). Claims 17 and 18 are dependent upon the independent claim 15. As discussed above, the independent claim 15 is allowable over the teachings of Valikai. Accordingly, claims 17 and 18 are also allowable as being dependent upon an allowable base claim.


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Claims 4 and 13 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Peel as applied to claims 1 and 10, in further view of U.S. Publication No. 2005/0103351 to Stomberg et al. (hereinafter Stomberg). Claims 4 and 13 are dependent upon the independent claims 1 and 10. As discussed above, the independent claims 1 and 10 are allowable over the teachings of Peel. Accordingly, claims 4 and 13 are also allowable as being dependent upon an allowable base claim.

For these reasons, Applicants respectfully submit that all of the claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at 414-271-7590 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,

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